



United States
Department of
Agriculture

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CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 06-04

Animal and Plant
Health Inspection
Service

Veterinary Services

Center for Veterinary
Biologics

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Subject: Withdrawal of Supplemental Assay Methods 310 and 311

To: Biologics Licensees, Permittees, and Applicants
Veterinary Services Management Team
Directors, Center for Veterinary Biologics
Area Veterinarians in Charge, VS
State Veterinarians

The purpose of this document is to notify veterinary biologics manufacturers that Supplemental Assay Method for Scoring Feline Calicivirus in Cats Following Challenge (SAM 310) and Supplemental Assay Method for Scoring Feline Rhinotracheitis Virus in Cats Following Challenge (SAM 311) will be removed from the list of approved SAMs, effective immediately. These SAMs describe scoring schemes that have been used to evaluate challenge studies of feline vaccines. The development of veterinary clinical research in recent decades demands that the clinical relevance of such studies be refined by specifying clinical outcomes more explicitly.

Biologics manufacturers who utilized these SAMs as guidelines for studies that are currently in progress may complete those studies as planned. Protocols and reports of future studies should not reference these documents. Protocols for Feline Calicivirus and Feline Rhinotracheitis Virus challenge studies should specify clinical outcomes in accordance with Veterinary Services Memorandum 800.200, General Licensing Considerations: Study Practices and Documentation, Section 2.3.9 and Veterinary Services Memorandum 800.202, General Licensing Considerations: Efficacy Studies, Section 3.6.

/s/ Richard E. Hill, Jr.

Richard E. Hill, Jr.
Director
Center for Veterinary Biologics



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